

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| First Named Inventor | : Anne Hover et al. | Group Art Unit: Examiner: |
| Appln. No. | : | |
| Filed | : | |
| Title | : BONE FRACTURE SUPPORT IMPLANT WITH NON-METAL SPACERS (As amended) | |
| Docket No. | : A227.12-0057 | |

PRELIMINARY AMENDMENT

Box Non-Fee Amendment
Assistant Commissioner for Patents
Washington, D.C. 20231

I CERTIFY THAT THIS PAPER IS BEING SENT BY U.S. MAIL, FIRST CLASS, TO THE ASSISTANT COMMISSIONER FOR PATENTS, WASHINGTON, D.C. 20231, THIS _____ DAY OF _____, 2001

PATENT ATTORNEY

Sir:

Prior to examination of the above-referenced application, please amend the application as follows:

IN THE TITLE

Please amend the title to read --BONE FRACTURE SUPPORT IMPLANT WITH NON-METAL SPACERS--.

IN THE SPECIFICATION

Replace the paragraph at page 1, line 4, with the following:

--The present application is a continuation of application number 09/289,324, filed April 9, 1999 and entitled INTRAMEDULLARY NAIL WITH NON-METAL SPACERS, now issued as U.S. Patent No. 6,XXX,XXX.--

IN THE CLAIMS

Please cancel claims 13-34.

Please amend claims 1, 3 and 10-12, and add new claims 35-47 such that pending claims 1-12 and 35-47 read as follows:

1. (Amended) An intramedullary nail for treatment of a fracture of a bone having a medullary canal extending longitudinally, comprising:

a nail structure extending longitudinally and formed of metal, the nail structure having a distal end with a tip for insertion into the medullary canal and a proximal end opposite the distal end, with a first window defined in an exterior side of the distal end of the nail structure, the first window having a first window longitudinal length and a first window width not equal to the first window longitudinal length; and
a first spacer formed of a non-metal material within the first window.

2. The intramedullary nail of claim 1, wherein the non-metal material of the first spacer is a bioresorbable material.

3. (Amended) The intramedullary nail of claim 1, wherein the nail structure further comprises:

a second window defined in an exterior side of the distal end of the nail structure opposing the first window permitting bicortical attachment with a bone fastener through the first and second windows, the second window having a second window longitudinal length and a second window width not equal to the second window longitudinal length.

4. The intramedullary nail of claim 3, wherein a second spacer formed of a non-metal material is within the second window.

5. The intramedullary nail of claim 4, wherein the nail structure further comprises a nail structure cannula defined longitudinally therein, wherein the first spacer and the second spacer are formed by a single insert with an insert cannula defined therethrough and aligned with the nail structure cannula.

6. The intramedullary nail of claim 3, wherein the nail structure includes a bend such that a longitudinal axis of the nail structure lies within a bisecting plane, and wherein the first window and the second window are symmetrically disposed on opposing sides of the bisecting plane.

7. The intramedullary nail of claim 1, wherein the first window longitudinal length is greater than the first window width.

8. The intramedullary nail of claim 1, wherein the nail structure further comprises a cannula defined longitudinally therein.

9. The intramedullary nail of claim 1, wherein the first spacer fills the first window prior to anchoring of a bone fastener.

10. (Amended) The intramedullary nail of claim 1, wherein an additional bone attachment hole is defined in a proximal end of the nail structure.

11. (Amended) The intramedullary nail of claim 1, wherein the nail structure includes an opening longitudinally spaced from the first window and in the distal end of the nail structure.

12. (Amended) The intramedullary nail of claim 1, wherein the non-metal material of the first spacer is a bioresorbable material;

wherein the first window longitudinal length is greater than the first window width;
wherein the nail structure further comprises:

a second window defined in an exterior side of the nail structure opposing the first window permitting bicortical attachment with the bone fastener through the first and second windows, the second window having a second window longitudinal length and a second window width less than the second window longitudinal length;

a bend such that a longitudinal axis of the nail structure lies within a bisecting plane, wherein the first window and the second window are symmetrically disposed on opposing sides of the bisecting plane;

a nail structure cannula defined longitudinally in the nail structure;

a through-hole defined through the distal end of the nail structure and longitudinally spaced from the first and second windows; and

an additional bone attachment hole defined in a proximal end of the nail structure;
and

wherein a bioresorbable insert provides the first spacer, the bioresorbable insert further providing a second spacer, the first spacer filling the first window and the second spacer filling the second window prior to anchoring a bone fastener through the first and second windows; and

wherein an insert cannula is defined through the bioresorbable insert and aligned with the nail structure cannula.

35. The intramedullary nail of claim 1, wherein the first spacer is formed of a non-metal material separately from the nail structure, the first spacer having outer dimensions which correspond to the first window shape, such that the first spacer is insertable into the first window and received by the first window to secure the first spacer relative to the nail structure.

36. A bone support assembly for treatment of a fracture of a bone, comprising:
a bone support implant formed of metal, the bone support implant having a first window extending therethrough, the first window having a first window shape; and
a first insert formed of a non-metal material separately from the bone support implant, the first insert having outer dimensions which correspond to the first window shape, such that the first insert is insertable into the first window and received by the first window to secure the first insert relative to the bone support implant.
37. The bone support assembly of claim 36, further comprising:
a bone fastener having a length sufficient to extend through the first insert in attachment with a bone, the bone fastener having a width small enough to be received in the insert and through the first window.
38. The bone support assembly of claim 37, wherein the bone fastener is insertable through the insert in the same direction as the insert is insertable into the bone support implant.
39. The bone support assembly of claim 35, wherein the outer dimensions of the first insert are sized to be received in the first window with a press fit.
40. The bone support assembly of claim 35, wherein the first insert fills the first window prior to anchoring of a bone fastener transversely through the first insert.

41. The bone support assembly of claim 41, wherein the first window has a first window longitudinal length, wherein the bone support implant has a proximal end and a distal end, wherein the first window is disposed in one of the distal end and the proximal end of the bone support implant, wherein the bone support implant has an opening defined in said one of the distal end and the proximal end, the opening being longitudinally spaced from the first window such that the first window and the opening are placed on the same side of the fracture, the opening having a longitudinal length which is less than the first window longitudinal length such that anchoring of a bone fastener transversely through the bone and into the opening can prevent dynamization while anchoring of a bone fastener transversely through the bone and into the first window can permit dynamization.

42. The bone support assembly of claim 35, wherein the non-metal material of the first insert is a bioresorbable material.

43. The bone support assembly of claim 41, further comprising:
a second insert formed of a non-metal material separately from the bone support implant and separately from the first insert, the second insert having outer dimensions which correspond to the first window shape, such that the second insert is insertable into the first window and received by the first window to secure the second insert relative to the bone support implant, the second insert having different mechanical or chemical treatment properties than the first insert.

44. The bone support assembly of claim 43, wherein the different mechanical or chemical treatment properties are selected from the group consisting of: different hardness, different rates of absorption, different active agents and different amounts of active agents.

45. A bone support assembly for treatment of a fracture of a bone, comprising:
a bone support implant formed of metal, the bone support implant having a proximal end and a distal end, the bone support implant having a first window extending therethrough and positioned closer toward one of the distal end and the proximal end, the first window having a first window shape with a first window longitudinal length, the bone support implant having an opening defined in the bone support implant and positioned adjacent the first window in said one of the distal end and the proximal end, the opening being longitudinally spaced from the first window such that the first window and the opening are placed on the same side of the fracture, the opening having a longitudinal length which is less than the first window longitudinal length; and
a first insert formed of a non-metal material receivable in the first window, such that anchoring of a bone fastener transversely through the bone and into the opening can prevent dynamization while anchoring of a bone fastener transversely through the bone and into the first window can permit dynamization.
46. A bone support assembly for treatment of a fracture of a bone, comprising:
a bone support implant formed of metal, the bone support implant having at least one window defined therein for exposure of a selected spacer;
a first spacer formed of a non-metal material, the first spacer being sized such that it is receivable in the window in an exposed position for transverse fastening through the bone support implant and through the first spacer with a bone fastener; and
a second spacer formed separately from the first spacer, the second spacer being sized such that it is receivable in the window in an exposed position for transverse fastening through the bone support implant and through the second

spacer with a bone fastener, the second spacer having different mechanical or chemical treatment properties than the first spacer.

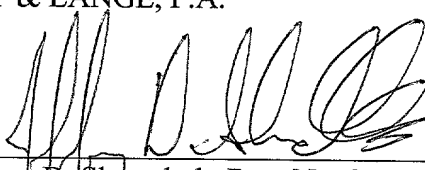
47. The intramedullary nail assembly of claim 45, wherein the different mechanical or chemical treatment properties are selected from the group consisting of: different hardness, different rates of absorption, different active agents and different amounts of active agents.

REMARKS

This Preliminary Amendment is submitted to further define the invention prior to examination. Entry of the Preliminary Amendment prior to examination is respectfully requested. The Examiner is invited to contact the undersigned at the telephone number listed below if such a call would in any way facilitate examination of the application.

Respectfully submitted,

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**APPENDIX:
MARKED UP VERSION OF SPECIFICATION AND CLAIM AMENDMENTS**

1. (Amended) An intramedullary nail for treatment of a fracture of a bone having a medullary canal extending longitudinally, comprising:

a nail structure extending longitudinally and formed of metal, the nail structure having a distal end with a tip for insertion into the medullary canal and a proximal end opposite the distal end, with a first window defined in an exterior side of the distal end of the nail structure, the first window having a first window longitudinal length and a first window width not equal to the first window longitudinal length; and

a first spacer formed of a non-metal material within the first window.

3. (Amended) The intramedullary nail of claim 1, wherein the nail structure further comprises:

a second window defined in an exterior side of the distal end of the nail structure opposing the first window permitting bicortical attachment with a bone fastener through the first and second windows, the second window having a second window longitudinal length and a second window width not equal to the second window longitudinal length.

10. (Amended) The intramedullary nail of claim 1, [wherein the first window is in a distal end of the nail structure, and] wherein an additional bone attachment hole is defined in a proximal end of the nail structure.

11. (Amended) The intramedullary nail of claim 1, [wherein the first window is in a distal end of the nail structure, and] wherein the nail structure includes an opening longitudinally spaced from the first window and in the distal end of the nail structure.

12. (Amended) The intramedullary nail of claim 1, wherein the non-metal material of the first spacer is a bioresorbable material;

wherein the first window longitudinal length is greater than the first window width;

[wherein the first window is in a distal end of the nail structure;]

wherein the nail structure further comprises:

a second window defined in an exterior side of the nail structure opposing the first window permitting bicortical attachment with the bone fastener through the first and second windows, the second window having a second window longitudinal length and a second window width less than the second window longitudinal length;

a bend such that a longitudinal axis of the nail structure lies within a bisecting plane, wherein the first window and the second window are symmetrically disposed on opposing sides of the bisecting plane;

a nail structure cannula defined longitudinally in the nail structure;

a through-hole defined through the distal end of the nail structure and longitudinally spaced from the first and second windows; and
an additional bone attachment hole defined in a proximal end of the nail structure;
and

wherein a bioresorbable insert provides the first spacer, the bioresorbable insert further providing a second spacer, the first spacer filling the first window and the second spacer filling the second window prior

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to anchoring a bone fastener through the first and second windows; and
wherein an insert cannula is defined through the bioresorbable insert and aligned with the nail structure cannula.

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